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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,799	TAKEDA ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *5,7-10,12 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6, 11, 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed September 23, 2004 in response to the Office Action of June 23, 2004 is acknowledged and has been entered. Claims 1-4, 6 and 11-21 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This application contains claims 5, 7-10 drawn to an invention nonelected with traverse in the response of October 2, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

The rejection of claims 1-4 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicants amendment to the claims deleting the reference to "partial peptides thereof" from the claim.

The rejection of claims 1-4, 6 and newly added claims 11, 13-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicants amendment clarifying that the kit comprises antibodies.

The rejection of claims 1-4, 6, 11 and13-18 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is maintained** for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an antibody against SSRV-related virus, the virus contains polypeptides having at least 80% sequence identity to the polypeptide encoding SEQ ID NO: 1-11. The claims do not require that the protein possesses any particular distinguishing feature, biologic activity, or conserved structure. Therefore, the claims are drawn to a genus of polypeptides that are defined only by sequence identity.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

> (MPEP 2163) The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998).

Claiming a product (an antibody) based on function (that binds to a sequence having 80% homology to SEQ ID) does not provide sufficient description of the product (the antibody). It has been well known that minor structural differences even among structurally related

compounds or compositions can result in substantially different biological or pharmacological activities. Therefore, structurally unrelated "molecules" encompassed by the claimed invention other than those disclosed in the specification as filed would be expected to have greater differences in their structural and functional characteristics and attributes. Mere idea or function (binding to a sequence having 80% homology to SEQ ID) is insufficient for written description; isolation and characterization of the critical epitopes at a minimum are required

> "a mere wish or plan" for obtaining an invention is not enough to comply with § 112, ¶ 1(*Regents of the University of California v. Eli Lilly & Co., 119* F.3d 559, at 1566).

The instant specification and claims do not provide sufficient functional and structural characteristics of the polyclonal antibodies that may bind a structure having 80% sequence similarity with the function of detecting SRSV, there is no disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the group, the disclosure of particular compounds is insufficient to describe the genus of molecules, encompassed by the claimed invention.

In this instance applicants are claiming polyclonal antibodies that recognizes SEQ ID NO: 1-11or recognizes peptides having 80% homology with SEQ ID NO: 1-11 where the antibody is a component of a kit for the detection of SRSV. There is some sequence similarity among the sequences set out in SEQ ID NO: 1-11. Antibodies that react with SEQ ID NO: 1 may not react with the sequences set out in SEQ ID NO: 2-11, it is understood that the claims are attempting to exclude cross reactive antibodies. Therefore, similarity among the sequences cannot function to define the structural feature necessary for the function of the antibodies in the kit. Therefore, the rejection is maintained.

The rejection of claims 1-4, 6 and newly added claims 11, 13-18 and rejected under 35 U.S.C. 112, first paragraph, because the specification **is maintained** for reasons of record. While being enabling for polyclonal antibodies that were produced by injecting a rabbit with a mixture of SRSV virus like particles (see specification page 29, lines15-25; example 5), does not reasonably provide enablement for antibodies obtained using peptides that are 80% homology to SEQ ID NO: 1-11.

Applicants' response has been fully considered but fails to persuade. Applicants' response is that the test of enablement is whether one of skill in the art "could make or use the invention." Applicants' arguments are directed to the individual processes used to make each component in the claimed kit. Applicants argument is that it is within the skill of the ordinary artisan to make changes to the structure disclosed in any of the sequences set out in SEQ ID NO 1-11 and that the process of making antibodies to any one of changed peptides would also be within the skill of the ordinary artisan. The prior art indicates that serum from patients that have recovered from one type of SRSV infection may be used to screen for other viruses having some structural feature in common with the virus that infected the patient. The instant claims however are attempting to exclude these cross reactive antibodies. What is unpredictable and remains unpredictable is whether an antibody that binds to a protein that has 80% structural similarity and does not have any cross reactivity to any of the other proteins in the kit actually will bind an epitope that recognizes an SRSV structure. The ability to perform the individual parts, makeing changes in the protein structure and producing an antibody to the new structure, may well be within the skill of the ordinary artisan. What is not within the skill of the ordinary artisan is to predict that an antibody that is made to a structure having 80% sequence homology will

reorganize an SRSV virus. This is required of the antibodies as they are to be used in a kit for the detection of an SRSV virus. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

The rejection of claims 1-4 and 6 under 35 U.S.C. 102(b) as being anticipated by Matson et al. (WO 94/05700) **is withdrawn** in view of applicants' amendments to the claims deleting the reference to "partial peptides thereof."

The rejection of claims 1-4 and 6 under 35 U.S.C. 102(e) as being anticipated by Estes et al. (U.S. Pat. No. 6,572,862 B1) **is withdrawn** in view of applicants' amendments to the claims deleting the reference to "partial peptides thereof."

The rejection of claims 1-4 and 6 under 35 U.S.C. 102(e) as being anticipated by Estes et al. (U.S. Pat. No. 6,156,833) **is withdrawn** in view of applicants' amendments to the claims deleting the reference to "partial peptides thereof."

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Lew et al. (Virology 1994) **is withdrawn** in view of applicants' amendments to the claims deleting the reference to "partial peptides thereof."

New rejection in view of applicants amendments to the claims:

Claims 1-4, 6, 11 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The instant claims are drawn to a kit comprising antibodies yet the antibodies do not react with "any of the peptides." It appears applicants are attempting to claim antibodies that do not cross-react (specification page 18, lines 9-18) this is not made clear in the claims as presently presented. Therefore, the instant claims are rejected because they fail to distinctly claim the subject matter of the invention.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 4/4/05